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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,010	10/25/2001	Jonathan W. Nyce	EPI-00312	5176

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EXAMINER
JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
1617	6

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/072,010	Applicant(s) NYCE, JONATHAN W.	
	Examiner Shaojia A. Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *80-127 and 159* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *80-127 and 159* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on January 22, 2003 in Paper No. 5 wherein 128-156 are cancelled, and claims 80-127 have been amended, and claim 159 is newly submitted. Currently, claims 80-127 and 159 are pending in this application.

Claims 80-127 and 159 are examined on the merits herein.

Applicant's remarks filed on January 22, 2003 in Paper No. 5 with respect to the rejection of claims 84-85 made under 35 U.S.C. 112 second paragraph for insufficient antecedent basis for this limitation, i.e., "active agent" of record stated in the Office Action dated May 7, 2002 have been fully considered and found persuasive to remove the rejection as to claims 84-85 since the base claim 80 recites "an agent".

Applicant's amendment filed on January 22, 2003 in Paper No. 5 with respect to the rejection of claims 84-85 made under 35 U.S.C. 112 second paragraph for insufficient antecedent basis for this limitation, i.e., "the formulation" of record stated in the Office Action dated May 7, 2002 have been fully considered and found persuasive to remove the rejection as to claim 98-107 and 111-119 since claim 97 which claims 98-107 and 111-119 are dependent from has been amended.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 98-107 and 120-127 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, of record stated in the Office Action dated May 7, 2002.

The expression " other therapeutic agents" in claim 106 renders claim 106 indefinite Applicant's remarks with respect to this rejection made under 35 U.S.C. 112 second paragraph for the expression " other therapeutic agents" have been fully considered but they are not deemed persuasive to remove the rejection. As discussed in the previous Office Action, this recitation is seen to fail to clearly set forth the metes and bounds of the patent protection desired. Therefore, the scope of claims is indefinite as to the composition encompassed thereby.

Claims 120-127 recite the limitation "the kit". There is insufficient antecedent basis for this limitation in the claim since claim 94 is drawn to the composition.

It is noted that claims 121-127 in the previous Office action should be claims 120-127. The typo error is regretted.

The following are new rejections necessitated by Applicant's amendment filed on January 22, 2003 in Paper No. 5, wherein the limitations in all pending claims as amended now have been changed. Therefore, the rejection made under 35 U.S.C. 103(a) and the rejection made under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-19 of U.S.

Patent No. 5,527,789, of record in the previous Office Action May 7, 2002 are withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 80-85, 94-100, 103-106 and 108 are rejected under 35 U.S.C. 102(b) as being anticipated by Langsjoen et al. (5,011,858 PTO-892).

Langsjoen et al. discloses a pharmaceutical composition comprising coenzyme Q10 (CoQ10, also known as an ubiquinone having the chemical formula herein when n =10) in a therapeutically effective amounts of 25-400 mg orally or parentally (see abstract, col.1 lines 11-12, col.2 lines 38-40 and 62-68) and a pharmaceutical carrier or diluent such as in oral dosage including capsules or in an emulsion (which are known to be liquid including aqueous and oil or solid particles) (see col.2 lines 68 and col.3 lines 46-47 and 58, claim 14 and 16) and in single or multi-dose form. The pharmaceutical composition therein further comprise other therapeutic agents such as AZT, amphotericin B, or isoinazide to be administered intravenously or intramuscularly (see Example 11-14 at col.6-7).

Thus, Langsjoen et al. anticipates claims 80-85, 94-100, 103-106 and 108.

Applicant is requested to note that it is well settled that "intended use" of a composition or product, e.g., treating lung inflammation, will not further limit claims drawn to a composition or product. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Claims 80-85, 94-103, 107-108, and 113 are rejected under 35 U.S.C. 102(b) as being anticipated by Brasey et al. (4,778,798 PTO-892).

Brasey et al. discloses a pharmaceutical composition comprising coenzyme Q10 or an ubiquinone having the chemical formula herein when n =10 in a therapeutically effective amounts, for example 11% with 2.5 mg/kg in combination with other therapeutic agents such as flunarizine orally (see abstract, col.2 lines 65-68, claims 1-3) and a pharmaceutical composition therein is formulated according to conventional techniques with a pharmaceutical carrier or diluent such as a flavoring agent, sugar, and a binding agent gelatin in oral dosage including tablets, capsules, dragees, sugar-coated pills, granulates, syrups or suspension (see col.3 lines 9-24), and patenteral formulation in sterile aqueous solutions (see col.3 lines 1-2)) and in single or multi-dose form.

Thus, Brasey et al. anticipates claims 80-85, 94-103, 107-108, and 113.

Claims 80-85, 94-99, and 111 are rejected under 35 U.S.C. 102(b) as being anticipated by Bertelli, Alberto (4,654,373, PTO-892).

Bertelli discloses a pharmaceutical composition comprising coenzyme Q10 or an ubiquinone having the chemical formula herein when n =10 in a therapeutically effective amounts, for example 10% topically, orally and patenterally (see abstract, col.2 lines 15-48) and a topical composition is formulated into creams, ointments, gel and lotions with a pharmaceutical carrier or diluent such as oil or suspension (see col.2 lines 43-65), and in single or multi-dose form.

Thus, Bertelli anticipates claims 80-85, 94-99, and 111.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 109-110, 112, and 114-127 even though these claims are not anticipated by Langsjoen et al. (5,011,858), Brasey et al. (4,778,798), or Bertelli, Alberto (4,654,373), as the 102(b) rejections set forth above, are rejected under 35 U.S.C. 103(a) as being unpatentable Langsjoen et al. (5,011,858), Brasey et al. (4,778,798), and Bertelli in view of Lieberman et al. (Pharmaceutical Dosage Forms, page 110).

The same disclosures of Langsjoen et al., Brasey et al., and Bertelli have been discussed above (see supra), especially they teach various formulation forms broadly

and various routes of administration broadly; for example, Brasey et al. teaches a pharmaceutical composition therein is formulated according to conventional techniques with a pharmaceutical carrier or diluent such as a flavoring agent, sugar, and a binding agent gelatin in oral dosage including tablets, capsules, dragees, sugar-coated pills, granulates, syrups or suspension.

The cited prior art does not expressly disclose that a pharmaceutical coenzyme Q10 composition is provided in sealed ampoules or vials, and inhalable, respirable or nasal formulation, the range of size of coenzyme Q10 in particles, and to put the same composition in to a kit.

Lieberman et al. teaches that a skilled artisan in pharmaceutical science would clearly knowledge that the granulation, determination of size, or size reduction of a solid pharmaceutical formulation, e.g., in tablet production, have several benefits, for example, as taught in a text book "Pharmaceutical Dosage Forms" Tables, (Volume 2) Ed. by Herbert A. Lieberman, Leon Leachman, and Joseph B. Schwartz (1989) at page 110.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ sealed ampoules or vials to store the pharmaceutical coenzyme Q10 composition, and to make inhalable, respirable or nasal formulation, and to granulate the coenzyme Q10 particles in range of size herein and to put the same composition in to a kit.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ sealed ampoules or vials to store the pharmaceutical

coenzyme Q10 composition, and to make inhalable, respirable or nasal formulation since the cited prior art teach various formulation forms broadly and various routes of administration broadly. According to conventional techniques to and to make inhalable, respirable or nasal formulation of the known active agents and to put the same composition in to a kit are considered well within the skill of artisan in pharmaceutical science, involving merely routine skill in the art.

Additionally, one having ordinary skill in the art at the time the invention was made would have been motivated to granulate the coenzyme Q10 particles in range of size herein since Lieberman et al. teaches that a skilled artisan in pharmaceutical science would clearly knowledge that the granulation, determination of size, or size reduction of a solid pharmaceutical formulation of known active agents.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 80, 86-93, and 159 are rejected under 35 U.S.C. 102(b) as being anticipated by Nyce (5,527,789, of record).

Nyce discloses a pharmaceutical composition comprising ubiquinone having the chemical formula herein and DHEA having the chemical formula herein in a therapeutically effective amounts and a pharmaceutical carrier or diluent (see claims 13-19)

Thus, Nyce anticipates claims 80, 86-93, and 159.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 80, 86-93, and 159 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-19 of U.S. Patent No. 5,527,789 (of record).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent are drawn to a pharmaceutical composition

comprising the dehydroepiandeosterone and ubiquinone with n being from 1 to 10, 6 to 10, or 10, and pharmaceutically acceptable carrier such as an aqueous or a solid carrier. The claim of the instant application is drawn to a pharmaceutical composition or formulation, or kit comprising the same dehydroepiandeosterone and ubiquinone with n being from 1 to 12, 1 to 10, 6 to 10, or 10, in the effective amounts, and pharmaceutically acceptable carrier such as an aqueous or a solid carrier, and this pharmaceutical composition or formulation, or kit may be further comprises other agents such as preservatives, antioxidants flavaoring agents, volatile oils, buffering agents, dispersants or surfactants.

Therefore, the claimed invention in claims 80, 86-93, and 159 is clearly seen to be anticipated by claims 13-19 of U.S. Patent No. 5,527,789.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
April 17, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER

4/25/03